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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,734	10/29/2003	Martin J. MacPheé	CI-0019C4	2649

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,734	MACPHEE ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10292003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/533,547, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Instant claims 1-3 all contain the limitation "wherein said effective rate is not constant for the duration of the sterilization procedure." The specification of 09/533,547 fails to support these limitations. Specifically, lines 10-12 on page 14 of the specification, teach "[p]referably, the rate of irradiation is constant for the duration of the sterilization procedure." While one may assert that a non-constant rate is merely a non-preferable embodiment of the instant invention, there is no teaching elsewhere in the specification of how or why one would choose a non-constant rate, or when choosing a non-constant rate, which rates to choose. Moreover, each and every example in the specification also teaches using only a constant rate of irradiation. Therefore, the specification of 09/533,547 fails to describe an effective rate that is not constant for the duration of the sterilization procedure.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4, 6, 12-17, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (US 5,418,130).

Platz et al. teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or

frozen before irradiation. See col.3, lines 38-47. The product may be irradiated at ambient temperature or in the deep frozen state. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al. specifically names albumin as a blood product that may be sterilized by the method (col.17, line 66 to col.18, line 17). Platz et al. further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Furthermore, one would have found it obvious to reduce the moisture content to the extent necessary to prevent hydroxyl formation during irradiation while maintaining viability. Such is readily determined through routine experimentation.

Platz et al. is silent with respect to a not constant dose rate. However, as the most common source of gamma radiation for microbial inactivation is ^{60}Co, a decaying source of radiation, the rate of radiation is constantly decreasing and thus is "not constant". It would have been obvious to one of ordinary skill in the art to use ^{60}Co as the gamma source in Platz et al. as it is the most widely known source.

6. Claims 5 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. in view of Horowitz et al (U.S. Patent No. 5,712,086).

With respect to claim 5, Horowitz et al. teaches a method of irradiating blood products wherein the blood products are first subjected to organic solvent fractionation in order to separate them (col.6, lines 17-21). As these same blood products are treated by the sterilization method

of Platz et al., it would have been obvious that, in order to obtain them, it would have been necessary to subject them to organic solvent fractionation.

As to claim 26, Horowitz et al. discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al. further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of Platz et al..

7. Claims 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. in view of Baquey et al. ("Radiosterilization of albuminated polyester prostheses").

Platz et al. is silent with respect to an effective rate at which to irradiate the albumin. Baquey et al. discloses a method for sterilizing albumin which has been coated on vascular prostheses wherein the albumin is irradiated with gamma radiation at a dose rate of 2600 rad/min (1.56 kGy/hr). See page 186,"Irradiations". Since Baquey et al. evidences a safe and effective dose rate for the gamma sterilization of albumin, it would have been an obvious dose rate for use in the method of Platz et al..

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. in view of Chanderkar et al. ("The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation").

Platz et al. is silent with respect to an effective rate at which to irradiate the albumin. Chanderkar et al. evidences gamma ray sterilization of fibrinogen (a blood product) using a dose

rate of 12,500 R/min (7.5 kGy/hr). As Chanderkar et al. teaches a gamma irradiation dose rate for the sterilization of a lyophilized sensitive blood product, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Chanderkar et al. in the method of Platz et al., as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

9. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. in view of Patel et al ("Effect of Gamma Radiation and Ethylene Oxide on Papain").

Platz et al. is silent with respect to an effective rate at which to irradiate the albumin. Patel et al. discloses a method for the sterilization of papain wherein the enzyme is irradiated with gamma radiation at a dose rate of 0.29 Mrad/hr (2.9 kGy/hr, "about 3.0 kGy/hr" or "about 2.0 kGy/hr"). See page 81, last paragraph. As Patel et al teaches a gamma irradiation dose rate for the sterilization of a sensitive biological material, it is deemed obvious to one of ordinary skill in the art to employ the dose rate disclosed by Patel et al in the method of Platz et al, as this dose rate has been determined to be effective in removing microbial contamination while preserving the activity of the sensitive biological material.

10. Claims 2, 3, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. in view of Horowitz et al..

Platz et al. teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) or frozen before irradiation. See col.3, lines 38-47. The product may be irradiated at ambient temperature or in the deep frozen state. The radiation used may be ionizing radiation, such as gamma radiation. See col.17, lines 57-60. Platz et al. specifically names albumin as a blood

product that may be sterilized by the method (col.17, line 66 to col.18, line 17). Platz et al. further discloses that the lyophilized product be kept under nitrogen or other inert gas (col.20, lines 54-60). It would have been obvious to keep the product under these conditions while irradiating as well, in order to avoid formation of hydroxyl radicals by the gamma radiation (col.3, lines 6-8). Moreover, it is deemed obvious to use argon as the inert gas since argon is a well-known inert gas. Furthermore, one would have found it obvious to reduce the moisture content to the extent necessary to prevent hydroxyl formation during irradiation while maintaining viability. Such is readily determined through routine experimentation. Platz et al. fails to teach the use of a stabilizer.

Horowitz et al discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of Platz et al.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 8 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 101 or 102 of copending Application No. 09/942,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims completely encompass the instant claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1, 4, 6, 7-17, and 23-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 103 of U.S. Patent No. 6,682,695 in view of Platz et al..

The patented claim fully encompasses the claimed subject matter except that it does not claim reducing the residual solvent content of the albumin or a non-constant dose rate. With respect to reducing the residual solvent, Platz et al. teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) before irradiation. See col.3, lines 38-47. As reducing the solvent content of the albumin removes hydroxyl sources which damage tissue during irradiation, it would have been obvious to do in the patented method.

As to the dose rate, since the most common source of gamma radiation for microbial inactivation is ^{60}Co, a decaying source of radiation, the rate of radiation is constantly decreasing and thus is "not constant". It would have been obvious to one of ordinary skill in the art to use ^{60}Co as the gamma source in the patented method as it is the most widely known source.

14. Claims 2, 5, and 18-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 103 of U.S. Patent No. 6,682,695 in view of Horowitz et al..

The patented claim fully encompasses the claimed subject matter except that it does not claim adding a stabilizer or a non-constant dose rate. Horowitz et al. discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al. further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of the patent.

As to the dose rate, since the most common source of gamma radiation for microbial inactivation is ^{60}Co, a decaying source of radiation, the rate of radiation is constantly decreasing and thus is "not constant". It would have been obvious to one of ordinary skill in the art to use ^{60}Co as the gamma source in the patented method as it is the most widely known source.

15. Claim 3 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 103 of U.S. Patent No. 6,682,695 in view of Platz et al. and Horowitz et al..

The patented claim fully encompasses the claimed subject matter except that it does not claim reducing the residual solvent content of the albumin, adding a stabilizer, or a non-constant dose rate. With respect to reducing the residual solvent, Platz et al. teaches a method for sterilizing blood products (col.1, lines 17-27) wherein the product may be lyophilized to less than 3% moisture (natural water and fluids removed) before irradiation. See col.3, lines 38-47. As reducing the solvent content of the albumin removes hydroxyl sources which damage tissue during irradiation, it would have been obvious to do in the patented method.

Horowitz et al. discloses a method of using ionizing radiation (such as gamma) in combination with a stabilizer (quencher) for the sterilization of sensitive biological material. See Abstract; col.6, lines 55-62. The quencher may be mannitol, glutathione, flavonoids, etc. See col.7, lines 3-8. Horowitz et al. further teaches that the stabilizers react with both free radicals and reactive forms of oxygen (col.6, line 66 to col.7, line 2), thereby protecting the biological material. For this reason, one of ordinary skill in the art would have found it obvious to use a stabilizer in the method of the patent.

As to the dose rate, since the most common source of gamma radiation for microbial inactivation is ^{60}Co, a decaying source of radiation, the rate of radiation is constantly decreasing and thus is "not constant". It would have been obvious to one of ordinary skill in the art to use ^{60}Co as the gamma source in the patented method as it is the most widely known source.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
19 February 2007